IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

United States, *ex rel.* JOHN DOE, BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA, Plaintiff, v. THE CHARLOTTE MECKLENBURG HOSPITAL AUTHORITY, a North Carolina Hospital Authority, and METROLINA NEPHROLOGY ASSOCIATES, P.A. a North Carolina Professional Corporation; Defendants.	Case No.: 3:16-cv-750 **COMPLAINT and JURY DEMAND** ***ORIGINAL COMPLAINT FILED IN CAMERA AND UNDER SEAL, PURSUANT TO 31 U.S.C. §3730(b)(2)*** ****DO NOT PLACE IN PRESS BOX**** ****DO NOT ENTER ON PACER****

NOW COMES PLAINTIFF-RELATOR, John Doe, by and through his attorneys, Charles H. Rabon, Jr., Daniel J. Finegan, and Gregory D. Whitaker, of Rabon Law Firm, PLLC, on behalf of the United States of America, and brings this action under 31 U.S.C. §§ 3729-3732 (the "False Claims Act") to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and himself and shows the Court as follows:

OVERVIEW

1. This is an action under the False Claims Act alleging that the Defendants submitted and/or caused to be submitted false and/or fraudulent claims to Medicare, Medicaid, and TRICARE in connection with certain medical procedures and services rendered by the Defendants and billed to Medicare, Medicaid, and TRICARE; that Defendant Charlotte Mecklenburg Hospital Authority included false, fraudulent, and improper charges on its

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Medicare Cost Reports that were submitted to the United States and which resulted in excessive reimbursements to that Defendant by Medicare; that Defendants engaged in violations of the Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and the Stark Law (42 U.S.C. § 1395nn); that Defendant Charlotte Mecklenburg Hospital Authority retaliated against Relator when it terminated him in the terms and conditions of employment because of his lawful acts done in furtherance of an action under the False Claims Act to stop violations of the Act by that defendant; and that Defendant Charlotte Mecklenburg Hospital Authority breached its employment contract with Relator.

PARTIES

2. Plaintiff-Relator John Doe ("Doe" or "Relator") is a resident of North Carolina.

3. Defendant The Charlotte Mecklenburg Hospital Authority ("CMHA") is a hospital authority organized and existing under the laws of North Carolina, with its corporate headquarters in Charlotte, North Carolina. CMHA may be served with process through its Registered Agent, Keith A. Smith, at 1111 Metropolitan Avenue Suite 600, Charlotte, North Carolina, 28204.

4. Defendant Metrolina Nephrology Associates, P.A., ("MNA") is a professional corporation organized and existing under the laws of North Carolina, with its principal office in Charlotte, North Carolina. MNA may be served with process through its Registered Agent, George M. Hart, at 1300 Baxter Street, Suite 215, Charlotte, North Carolina, 28204.

JURISDICTION AND VENUE

5. This action arises under the False Claims Act, 31 U.S.C. §3729, *et seq*.

6. Jurisdiction over this action is conferred upon this Court by 31 U.S.C. §3732(a) and 28

U.S.C. §1331 in that this action arises under the laws of the United States. The Court has supplemental jurisdiction under 28 U.S.C. §1367 as to Relator's state law claim for breach of contract.

7. Venue is proper in this district pursuant to 31 U.S.C. §3732(a), which provides that "any action under §3730 may be brought in any judicial district in which the Defendant or, in the case of multiple Defendants, any one Defendant can be found, resides, transacts business, or in which any act proscribed by §3729 occurred."

8. The Plaintiff and Defendants all reside in this District. Further, all or substantially all of the proscribed acts, which are the subject of this action, occurred in the State of North Carolina within this judicial district.

9. Venue is proper in this district pursuant to 28 U.S.C. §1391(b) and (c).

10. There are no bars to recovery under 31 U.S.C. §3730(e). Specifically, substantially the same allegations as those alleged in this suit have not been publicly disclosed in a federal criminal, civil, or administrative hearing in which the Government or its agents were a party, or in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, or from the news media. In the alternative, Relator is an original source as defined in 31 U.S.C. §3730(e). Relator has knowledge that is independent of and materially adds to any publicly disclosed allegations or transactions..

FACTUAL ALLEGATIONS

Relator's Employment and Relationship with Defendants

11. Plaintiff-Relator John Doe (hereafter "Doe" or the "Relator") is a resident of the State of North Carolina. Relator is a former employee for Defendant CMHA, having been employed there from 1993 through 2013.

12. Relator was originally hired as a full-time surgeon with CMHA's Charlotte flagship facility, Carolinas Medical Center ("CMC"). In 2001, he was elected to a term as Chief of the Department of General Surgery. As the time of his firing in 2013, Relator was employed as CMC's Director of Transplantation at the CMC Transplant Center, as well as Medical Director of CMC's transplant organ procurement organization – LifeShare of the Carolinas, Inc. (hereafter the "OPO"), positions that, by then, he had held for many years.

13. CMC has performed organ transplants since 1970. Since approximately 1993, all transplant procedures at CMC have been conducted under the Department of General Surgery.

14. Currently, CMC performs approximately 200 organ transplants annually, which include heart, kidney, pancreas, and liver transplants. In the most recent year for which complete data is available (2015), the CMC Transplant Center performed 103 kidney transplants, 63 liver transplants, 5 kidney/pancreas transplants, and 31 heart transplants.

15. Patients who receive transplanted organs require ongoing monitoring, care, and treatment following the transplant surgery. This includes initial follow ups with surgeons, as well as extensive lab work to continuously test organ function and viability. For kidney transplants, lab work is typically done on a schedule of 2 times per week for the first month, 1 time per week for months 2 through 6, and every other week for months 7 through 12.

16. As described later in this Complaint, the federal government provides coverage for individuals with End Stage Renal Disease ("ESRD") for defined periods of time, and including dialysis treatments and transplants. "End-Stage Renal Disease (ESRD) is a

medical condition in which a person's kidneys cease functioning on a permanent basis leading to the need for a regular course of long-term dialysis or a kidney transplant to maintain life. Beneficiaries may become entitled to Medicare based on ESRD. Benefits on the basis of ESRD are for all covered services, not only those related to the kidney failure condition." https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/End-Stage-Renal-Disease-ESRD/ESRD.html If the beneficiary has Medicare only because of ESRD, Medicare coverage continues for 12 full months after the cessation of dialysis treatments, or 36 months after the month in which the beneficiary received a kidney transplant.

17. Medicare pays for kidney transplants under what is called a "Global Surgical Package." As explained by CMS,

> *The global surgical package, also called global surgery, includes all necessary services normally furnished by a surgeon before, during, and after a procedure. Medicare payment for the surgical procedure includes the preoperative, intra-operative, and post-operative services routinely performed by the surgeon or by members of the same group with the same specialty. Physicians in the same group practice who are in the same specialty must bill and be paid as though they were a single physician.*

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/GloballSurgery-ICN907166.pdf

18. Kidney transplant surgery is considered to be a "major procedure" for which the Global Surgical Package includes one day pre-operative service, the procedure day, and 90 days immediately following the day of the surgery. Id.

19. The monitoring, care, and treatment that is provided following the transplant surgery and during the 90 day period paid by Medicare under the Global Surgical Package is referred to as the "post-operative clinic." Medicare expects, and qualifies payment, for post-operative services to the same entity or group that receives payment for the Global Surgical Package. In other words, since Medicare already pays for post-operative clinical services under the Global Surgical Package, Medicare expects not to have pay again for post-operative clinical services provided by another entity.

Defendants' "Dual Location" Model for Post-Transplant Clinic, CMS' Statement of Deficiencies, and CMC's Response

20. Notwithstanding that CMC has performed kidney transplants for decades and received payments through Medicare under the Global Surgical Package manner of payment, CMC has lacked an on-site post-transplant clinic for its kidney transplant patients. Instead, CMC essentially "farms out" the post-transplant clinic responsibilities to the nephrology clinic that is its main source of kidney transplant referral patients.

21. This arrangement has caused significant problems and was identified as a contributing root cause for a series of adverse outcomes (unusually high numbers of patient deaths and graft losses) in 2010. As a result of those negative outcomes, CMS sent a letter to CMC advising that it was no longer in compliance with Conditions of Participation: 42 C.F.R. 482.82 – Data Submission, Clinical Experience, and Outcome Requirements for Re-approval of Transplant Centers.[1] In its response letter, CMC described the adverse events

[1] Relator does not currently possess a copy of this communication from CMS; however, it almost certainly was a CMS Form 2567, Statement of Deficiencies. When a Form 2567, Statement of Deficiencies is sent, the provider must respond with a Plan of Correction within 30 days or face termination as a Medicare provider. CMC utilized outside consultants to assist in preparing its response and statement of mitigating factors, which is largely based on a study recommendation by outside consultants that CMC retained in 2010, anticipating that CMS would take action in the future.

(patient deaths and graft losses) as an "unacceptable spike in mortality." CMC described the dual location arrangement for post operative care as "unique": "The CMC Kidney Transplant program has a unique model for post-transplant care. The care of the recipient post-discharge occurs primarily in two locations – one for nephrology care and one for surgical care.... It was felt that this dual-location care model produced potential difficulties in communication between multidisciplinary team members, specifically in regard to the management of complex cases."[2]

22. In its response letter to CMS, CMC continued: "Process Improvement: This problem is being addressed through the addition of staff, the consolidation of the post-transplant clinic in a single location and approval for a hospital based midlevel provider to be dedicated to the kidney transplant program." CMC went on to state that "[t]he program is currently evaluating options and working on a plan to consolidate care in one location for all aspects of post-transplant patient management."

23. Relator is not aware of any other transplant program in the country that has its principal post-transplant patient management clinic in a location apart from the transplant center. As a specific example of why the "dual location" model is so problematical is the fact that as soon as the transplant patient is discharged from CMC, the CMC physicians and transplant team cannot even look at the patient's lab work. The first labs that are drawn following transplantation are done at MNA, because there is no post-transplant clinic at the CMC Transplant Center.

24. CMS accepted CMC's plan of correction, based in part on its representation that post-transplant patient management clinic would be consolidated at the CMC Transplant

[2] The post-operative clinic – i.e., the post-transplant patient management clinic at which all follow up monitoring, care, and treatment following the transplant surgery is handled – is done at the premises of Defendant MNA and by MNA physicians, not by the physicians at the CMC Transplant Center as CMC expects.

Center. In fact, however, that was never done.

25. Upon information and belief, Defendant MNA owns and controls the only substantial group of nephrology clinics and related medical practice in the greater Charlotte metropolitan area and surrounding counties.

26. To ensure dominance of the entire Charlotte metropolitan nephrology market, MNA has acquired or merged with its few competitors in the Charlotte metropolitan area – Southeast Renal Associates and Central Carolina Nephrology in 2010 and 2013, respectively.

27. CMHA does not operate any independent nephrology practice in the Charlotte metropolitan area.

28. CMC Transplant Center receives approximately 60% of all its patient referrals for kidney transplants from MNA.

29. All or substantially all of the services CMC provides to patients pursuant to MNA referrals are covered as "Designated Health Services" pursuant to 42 U.S.C. § 13955nn(h)(6).

30. CMC has entered into a unique and highly unorthodox arrangement whereby CMC pays money to MNA, relies on MNA to provide all post-transplant care at MNA's Charlotte area clinics, and refers post-transplant care responsibilities to MNA and its physicians.[3]

CMC's "Special Relationship" with MNA

31. On information and belief, CMC also pays MNA and/or certain of its physicians as

[3] MNA is a privately held, physician owned nephrology practice. It is not among the types of Medicare reimbursable facilities that are required or permitted to file Medicare Cost Reports to obtain reimbursement for certain otherwise unreimbursed costs in connection with participating in the Medicare program. CMC's 2012 MCR shows that it claimed amounts for "post transplant clinic", though it is not entirely clear what this was for. However, CMC in fact did not operate a post-transplant clinic. This indicates that CMC's MCR with regard to post-transplant clinic costs are false.

independent contractors to provide lectures to staff and residents, and to allow residents to follow the physicians around during patient encounters. CMC also has contracts with some MNA physicians to hold the title of appointment such as Chairman of Nephrology and Internal Medicine Carolinas Medical Center Mercy, Dialysis Medical Director of Carolinas Medical Center Mercy, Medical Director of the Kidney Dialysis Unit at Carolinas Medical Center-Union campus, President of Medical & Dental Staff at CMC, Chairman CMC Credentialing Committee, Chairman of CMC Medical Executive Committee, Medical Director of Kidney Dialysis Unit at Carolinas Medical Center-Pineville campus, Medical Director CMC Kidney Dialysis, and Assistant Director CMC Kidney Transplant Program.

32. Upon information and belief, CMC and MNA have entered into negotiations and agreements for how to further cooperate in expanding the region in which MNA offers services to other CMHA system hospitals, and whereby MNA can replicate the nephrology market dominance it has attained in the Charlotte metropolitan area.

33. This market dominance of MNA has a detrimental effect on the overall health and needs of the at-risk community in the Charlotte metropolitan area. CMC conducted internal evaluations of its transplant services as early as 2010 that determined that the lack of nephrology clinics in its service areas were causing service bottlenecks, and that more nephrology clinics were needed to adequately service the population.

34. In its same internal evaluations, CMC also determined that the only means by which it could grow the volume of patients it treats for transplant services was to increase the size of its waitlist. The only way to increase the size of its waitlist was to increase the number of referrals it received. Given that all or substantially all of its transplant referrals come

from MNA, the resultant conclusion from this internal evaluation is that the only way for CMC to grow its transplant program is to increase its relationship with MNA and assist MNA in acquiring more patients that can be referred to CMC's transplant waitlist.

35. During his tenure as Director of Transplantation and as Medical Director of CMC's OPO, Relator repeatedly raised concerns about CMC's lack of an on-site post-transplant care facility, its overly dependent relationship with MNA, MNA's improper influence and control over CMC's transplant operations, questionable referral arrangements existing by and between CMC and MNA, and questionable Medicare billing practices that appeared to be taking place relating to CMC's relationship with MNA.

36. Relator was repeatedly informed both by CMHA administrators and by the president of MNA that the relationship with MNA was vital to CMC as MNA was the largest referral source for kidney transplant surgeries occurring at CMC's transplant center and, essentially, that this relationship would remain in place "as is."

37. Many times over the course of several years, Relator expressed to CMC management and to management of MNA that the post-transplant clinic needed to be consolidated into a single location at the CMC Transplant Center – just as post-transplant clinics are expected by Medicare to be operated and as they are in fact operated at other transplant centers. Each time Relator raised this issue, he was berated both by CMC management and by the physician owners who were the management of MNA that the status quo would remain in place.

38. At least as recently as 2012, when Relator raised this to MNA's president, Dr. George Hart, Dr. Hart replied by saying that if there was to be a change in the relationship between CMC and MNA, that MNA would stop making transplant referrals to the CMC

Transplant Center and instead that MNA would send their transplant patients to either Wake Forest Baptist Medical Center Transplant Center, the UNC Chapel Hill Kidney Center, or to Duke University Hospital's Kidney Transplant Program – which are the other kidney transplant centers in North Carolina.

39. These conversations with Dr. Hart took place in the context of discussions around the "mitigating factors" response to CMS. Relator was also told around this time that there was no contractual arrangement between CMC and MNA whereby CMC paid MNA directly for performing post-transplant clinical services[4]. Dr. Hart made it clear that it was extremely lucrative to MNA for it (MNA) to operate the post-transplant clinic, and that this arrangement would not changed. This arrangement included MNA separately billing for post-transplant clinical services, despite the fact that CMC already had been paid under the Global Surgery Package.[5] The outcome of these discussions was that CMC management entirely supported the MNA position.

40. Prior to Dr. Hart saying these things, the two previous physician presidents of MNA had said, more or less, the same thing, one of them adding that if the relationship were changed, CMC would have to pay MNA an amount of money in the "millions" for ending their deal.

41. Relator was also assured over the course of several years that the post-transplant clinic would ultimately be consolidated on-site at CMC. Despite these assurances, the post-

[4] This specific conversation was either with Dr. Hart, or with Dr. Chris N. Fotiadis, of MNA that there was "no contract" for MNA to provide patient services or to be on call during the post-transplant clinic window of time (i.e., the 90 days post transplant as described in the Global Surgery Package payment period). MNA physicians told Relator that they would "lose control" and "lose revenue" if they gave up providing coverage during this timeframe. This strongly points to the fact that MNA was billing Medicare for services on top of, and that should have been covered under, the Global Surgery Package payment from Medicare.

[5] Further, under the Global Surgery Package payment arrangements by the government, Medicare considers the transplant patients to be patients of CMC. CMC has abdicated its patient duties for the post-transplant period to MNA.

transplant clinic was never consolidated on-site at CMC and the highly unorthodox use of MNA's off-site facilities as CMC's post-transplant clinic continues.

42. Patients diagnosed with end-stage renal disease (i.e. including patients eligible for transplant operations as addressed in this Complaint) automatically qualify for Medicare coverage with only a few restrictions as to the timing the coverage begins for each such patient. Accordingly the vast majority, if not substantially all of MNA's patients are covered by Medicare for the medical services MNA provides and for transplant services provided by CMHA.

43. With respect to organ transplant services, the Center for Medicare and Medicaid Services ("CMS") provides one global payment for related care, including for 90 days of post-transplant care.

44. In or around 2010, CMC had sufficient unsatisfactory patient outcomes from their transplant services such that in November 2012, CMS issued a notice of non-compliance with 42 CFR 482.82 - a condition of participation with CMS.

45. CMC was aware of the issues prior to the formal notice, and had conducted an internal Quality Assessment and Process Improvement initiative ("QAPI") to identify deficiencies in the transplant services regime and propose improvements.

46. The findings included in the QAPI were thereafter used in a formal request for continued approval to participate with CMS due to mitigating factors related to the unsatisfactory outcomes (the "Mitigating Factors Request"). The Mitigating Factors Request was submitted to CMS on or around November 26, 2012.

47. Two of the six problematic processes identified in the Mitigating Factors Request dealt directly with CMC and MNA's post-transplant care arrangement. Issues identified

included the fact that the majority of transplant graft failures occurred during the first 90 days after surgery, higher rates of infectious disease occurred due to lack of infectious disease doctors overseeing the recovery, and the fact that the off-site post-transplant clinic produced problems in the management of complex cases.

48. Among other problems created by utilizing MNA facility as its post-transplant clinic, CMC lacks access to the electronic medical records of patients for all services provided/assessment made through MNA. MNA medical records are not accessible by the CMC medical records system.

49. One of the substantial process improvements promised in the Mitigating Factors Request was that the use of the off-site MNA post-transplant clinic would cease, and that a fully functional post-transplant clinic would be established on-site at CMC. Despite its promises in the Mitigating Factors Request, this on-site clinic has never been created.

50. The sole reason the post-transplant clinic has never been moved on-site to CMC is because it generates substantial revenue for MNA and MNA exercises undue control and influence over CMC due to MNA's role as the referral source for 60% of CMC's kidney transplant surgery operations.

Medicare Cost Reporting Fraud by CMC

51. By participating in CMS and receiving payment for services rendered to Medicare and Medicaid recipients, CMHA is required to file a Medicare Cost Report for its CMC operations ("Cost Report") each year. Hospitals participating in the Medicare program are required to file Medicare Cost Reports annually. 42 U.S.C. § 1395g. Medicare Cost Reports are filed on Form CMS-2552.

52. The Medicare Cost Report, CMS Form 2552, requires a certification by an officer or

administrator of the Hospitals that the cost report is "true, correct, complete" and "prepared . . . in accordance with applicable instructions, except as noted." It also requires a certification that "I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations." The purpose of the Medicare Cost Report is to provide information supporting the hospital's claim for reimbursement by Medicare (CMS) for certain administrative and other indirect costs that are necessary for the operation of the hospital, but which are not directly reimbursable through fees for services. When the Medicare Cost Report contains false, overstated charges, a false claim has been submitted to the United States.

53. Despite the fact that CMC does not operate an on-site post-transplant clinic as promised in the Mitigating Factors Request, the 2012 and other certified Cost Reports include expenses, allocations and adjustments as if CMC did, in fact, operate an on-site post-transplant clinic.

54. CMC gave nominal administrative titles to each transplant surgeon on its staff for the sole purpose of inappropriately allocating a portion of their salaries as administrative expenses and included these amounts on its Cost Reports.

55. CMC inappropriately required all transplant surgeons to complete Medicare Cost Report timesheets and included these amounts in its Cost Reports, despite the fact that these timesheets should not have been completed for surgery related time.

56. CMC, through its Medicare Cost Report accountant, instructed CMC physicians on what to include on their timesheets (which were used ultimately to provide the backup data for

the MCR's). Physicians were told to include things on timesheets that amounted to time exaggerations and to include things under pre-transplant administration time that were in excess of allowed limits. Relator complained at the impropriety of doing this, since he knew that this data would be used in MCR's and would be used to ask the federal government to pay reimbursements to CMC to which it was not entitled.

57. Upon information and belief, CMC inappropriately accounted for Relator' entire salary as an expense on its annual Cost Reports. In its 2012 Cost Report, CMC reports an amount approximately identical to Relator's compensation as a salary expense allocated from CMC's surgery department to its OPO.

Double Billing for Services

58. Upon information and belief, CMC and its OPO are bundled together into CMC's annual Cost Report in this way in order to inappropriately include and hide expenses that would otherwise not be properly allocated into the Cost Reports.

59. Upon information and belief, CMHA and MNA have inappropriately billed for services rendered related to transplant surgeries and post-transplant care. Among other things, MNA physicians would routinely visit patients in surgical recovery on-site at CMC and submit separate bills for their visits. These visits should have been covered under the 90 day global care payment provided by CMS.

60. In a meeting with CMC management and MNA physicians held in the late spring or early summer 2013, Relator again (unsuccessfully) raised the issue of the need to consolidate the post-transplant clinic to the hospital. The discussion that ensued led to a discussion regarding CMC's participation in the 340B Drug Discount Program.

340B Drug Discount Program Fraud

61. The 340B Drug Discount Program is a U.S federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. The intent of the program is to allow covered entities to "[s]tretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." See http://www.hrsa.gov/opa/

62. Health care organizations/covered entities eligible to participate in the 340B Drug Discount Program are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. Id. CMC is an organization that is eligible to participate, but MNA is not.

63. In the meeting involving CMC management and MNA physicians, held in the late spring or early summer 2013, referenced above, Relator expressed concerns about the legality of MNA writing prescriptions for transplant patients through the post-transplant clinic and then directing that the patients fill the prescriptions at the CMC 340B pharmacy, where they could obtain substantial discounts.

64. Relator had previously been informed that it was the standing practice of MNA physicians to direct that transplant patients to have their prescriptions filled at the CMC 340B pharmacy, primarily because CMC routinely waived upfront co-pays for these patients, and made no effort (or only sham, token efforts) to bill for the co-pays on the

back end and, instead, routinely failed to collect and therefore waived co-pays[6]. Such an arrangement would be highly beneficial to both MNA and CMC. For MNA, it would be able to represent to its patients that they would receive expensive immunosuppressant drugs essentially for free. This would give MNA a competitive advantage in gaining patients versus other nephrology practices who manage patients that are kidney transplant candidates. This also amounts to an indirect kickback to MNA and its physicians. For CMC – by waiving upfront co-pays and then routinely not seeking to collect the co-pays later – the arrangement ensured the referrals of a steady supply of transplant patients to the CMC Transplant Center. The co-pays that were not collected upfront, and which were then effectively waived altogether because CMC did not seek to collect on the back end, amounted to as much as $500 to $1,000 per month, per patient. The routine waiver of co-pays, without an individualized determination of financial hardship or exhaustion of reasonable collection efforts, also amounted to a kickback to the Medicare beneficiaries who received their transplants at CMC.

Other Questionable Practices

65. When Relator tried to discuss these issues at the meeting involving CMC management and MNA physicians, held in the late spring or early summer 2013 and point out the impropriety that MNA was not an eligible outpatient facility that was permitted to write prescriptions that were fillable at the CMC 340B pharmacy, he was immediately cut off by CMC management present at the meeting and informed that there would be no further discussion on that topic.

[6] Waiving co-pays for Medicare beneficiaries is permissible on a case-by-case basis, when there is an individualized determination of financial hardship or exhaustion of reasonable collection efforts. Waiving co-pays as a matter of course and practice (including making sham collection efforts and then writing off the unpaid co-pays) is not permitted and gives rise to False Claims Act liability.

66. Upon information and belief, CMC inappropriately agreed to provide free annual check-ups for patients who were to be live kidney donors in order to induce MNA to provide more referrals to CMC transplant surgery operations. This practice also was improper, because it amounted to an indirect kickback to MNA (as an incentive to refer patients).

67. Relator repeatedly raised concerns with CMC administrative officers regarding the above-described practices during his tenure as Director of Transplantation and Medical Director of CMC's OPO. In February 2012, Relator met with Sarah Herring and Dave Bowman, (both CMHA employees responsible for CMC's Medicare Cost Report accounting and compliance), to discuss his concerns with the Medicare Cost Report time allocation practices.

68. In this meeting, Relator raised the above-described issues about how CMHA was accounting for physician time at CMC, but was informed to continue reporting his time as instructed.

69. Between 2010 and 2012, in an effort to increase hospital revenue and billable services from its clinical physicians, CMC began instituting a new "productivity-based" compensation model described as "relative value units" (the "RVU System").

70. The RVU System was extremely controversial among CMC physicians amid concerns that compliance with CMC demands for productivity, along with incumbent administrative time demands, could not be accommodated unless patient safety were jeopardized or fraudulent billing practices were tolerated.

71. Relator repeatedly raised concerns with CMC administrative officers regarding the RVU System and the impossible demands it placed on surgeons regarding billing requirements. In a meeting in the early fall of 2012, Relator met with Robin Surane, CMHA Vice

President for CMC's transplant program and OPO. At this meeting they discussed how approximately 60% of Relator's time was historically spent on administrative tasks, and 40% spent billing for clinical services. In order to perform under the new RVU System, Relator would have to almost double his billable services rendered each year while maintaining his same administrative responsibilities.

72. When Relator asked how this could possibly be done, Ms. Surane responded that Relator should be more like a certain CMC physician known among clinical staff for excessively high billables. This physician was known to clinical staff to violate Medicare rules by, among other things, billing for surgeries where he did not personally participate.

73. Ms. Surane made it clear that in order to comply with the new RVU System, each physician was required to bill in excess of $2 million each year regardless of circumstances or administrative responsibilities.

74. In a follow up meeting on the subject with Dr. Scott Furney, Chair of the Department of Medicine, the issue of billable productivity again came up as did the reference to the same physician known for excessively high billables. Relator made it clear that he would not engage in such billing practices and that he would not support other CMC physicians engaging in such behavior. Relator explicitly stated at this meeting that he would truthfully report the issues in context with any government investigation into the hospital's billing practices.

75. Around the same time, in October 2012, CMC management had a meeting with MNA physicians regarding CMC's Mitigating Factors Request to CMS. Relator was in attendance at this meeting. The purported purpose of the meeting was for both CMHA and MNA to "clear the air" regarding any disagreements so they could present a "united

front" to CMS regarding the continuation of the CMC transplant program. Relator later learned that this meeting was called by CMC management so that Relator could vent his frustrations and disagreements with the arrangements between CMC and MNA and that, by doing so, Relator would be less likely to raise criticisms directly to CMS during the "mitigating factors" conference call with CMS.

76. Due to the promised reforms to the transplant program included in the proposed Mitigating Factors Request, and in particular due to the promised relocation of the post-transplant clinic, Relator agreed to move forward with the Mitigating Factors Request.

77. In March, 2013 CMS informally communicated a favorable decision on CMC's Mitigating Factors Request. Thereafter, Relator noticed that the promised reforms and process improvements began to lag or cease altogether. Notably, at this point the efforts towards the relocation of the post-transplant clinic were resisted and opposed by MNA and all efforts to complete the promised reform ultimately ceased.

78. Relator became openly critical of the failure to comply with promised reforms at this point and with MNA's undue influence over the CMC transplant program due to the volume of referrals it provided. Relator commented at more than one meeting with Lisa McCanna (CMHA Assistant Vice President for Transplant Services and CEO of CMC's OPO) and Joyce Korzen (CMHA Vice President of Operations), during the spring/summer of 2013 that CMC needed to inform CMS of its failure to comply with its proposed reforms in its Mitigating Factors Request. In response Relator was informed that under no circumstances would CMC do so.

79. In a meeting during the summer of 2013 with Joyce Korzen, Lisa McCanna, MNA physicians and CMHA counsel, Relator again raised the issue of the relocation of the

post-transplant clinic and also the issue of MNA physicians improperly utilizing CMC's 304B Drug Discount Program as described hereinabove. The CMC/CMHA officers present refused to discuss these matters.

Relator is Terminated for Engaging in Protected Activities to Expose Fraud

80. Without any prior notice or warning, Relator' employment was terminated on October 28, 2013 at a meeting that he had requested to address irreconcilable demands between his administrative responsibilities as Director of Transplantation and CMHA's newly implemented RVU System.

81. Prior to this point, Relator had always received performance reviews indicating his performance had never been less than satisfactory, and was more often considered exceptional.

82. At the meeting at which he was terminated, Relator was informed that the alleged grounds for his immediate termination were that he had falsified time records relating to his vacation time. CMHA representatives claimed that Relator had wrongfully allocated three days of his vacation time as education leave in July 2013.

83. The time sheet form for claiming the time off included vacation time and education leave on adjacent boxes, and upon information and belief, the wrong box had been inadvertently checked for the days in question. Pursuant to the terms of his Employment Agreement, CMHA was required to provide notice and an opportunity to cure any such defects. CMHA informed Relator he was terminated immediately with no notice, no opportunity to cure any mistake in the time records, and no payment of his contractual right to 90 days pay after notice of termination.

84. In fact, the reason given for Relator termination was purely pretextual and Relator was

terminated for no valid reason, but rather due to his lawful acts in furtherance of efforts to stop violations of the False Claims Act and the commission of fraud by CMC and MNA:

a. his inquiries into, and refusal to act complicitly with, CMHA and MNA's inappropriate relationship, including but not limited to unlawful Medicare billing practices, unlawful Stark Law violations through kickbacks for referrals, and efforts to monopolize the nephrology market in the greater Charlotte Metropolitan area;

b. his attempts to move the post-transplant clinic on-site at CMC as promised in CMHA's Mitigating Factors Application;

c. his inquiries into MNA and CMHA's referral and post-transplant treatment arrangements; and

d. his inquiries into MNA and CMHA's inappropriate use of the discount drug prescription program under the 340B program.

Improper Relationship/Stark Law Act and Anti-Kickback Act Violations

85. The improper relationships between the Defendants described herein, including the contracts for MNA physicians for doing minimal work, the knowledge and permissiveness of MNA physicians performing (and billing for) post-transplant services that are already paid for under Global Surgery Packages, the arrangements by which MNA physicians are permitted to prescribe under the 340B Drug Discount Program, including the waiver of co-pays, and the inclusion of MCR costs for post-transplant clinic when in fact CMC Transplant Center does not operate a post-transplant clinic, all constitute improper financial relationships with physicians under the Stark Act and kickbacks to induce referrals under the Anti-Kickback Statute. As such, all claims

submitted in consequence of those tainted referrals are false under the federal False Claims Act.

86. As a direct and proximate result of the false and fraudulent acts described above, the Defendants have knowingly submitted false claims to the United States, have submitted false claims based on false records, have conspired to commit violations of the False Claims Act and, as to defendant CMHA, wrongfully terminated Relator in violation of his right not to be retaliated against for his effort to expose these frauds.

87. In having submitted claims for payment, directly and indirectly, under the Medicare program, Defendants both expressly and implicitly certified to the Government that they were in compliance with all material requirements that would entitle them to payment, when in fact they were not.

88. The violations that have occurred as a result of Defendants' actions, described herein, are material to the United States. In having made payments under the Medicare to these Defendants, the Government lacked full and complete knowledge of Defendants' violations. The Government consistently and routinely denies payment of claims submitted under the circumstances described in the Complaint.

FIRST CLAIM FOR RELIEF
(FALSE CLAIMS – 31 U.S.C. §3729(a)(1)(A))

89. The allegations of all paragraphs in this Complaint are incorporated by reference.

90. In performing the acts described above, the Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly presented, and/or caused to be presented, to an officer or employee of the United States Government, false or fraudulent claims for payment or approval under Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(A).

91. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

92. Additionally, the United States is entitled to penalties of up to $11,000 for each and every violation of 31 U.S.C. §3729(1)(A) by the Defendants.

SECOND CLAIM FOR RELIEF
(FALSE STATEMENTS – 31 U.S.C. §3729(a)(1)(B))

93. The allegations of all paragraphs in this Complaint are incorporated by reference.

94. In performing the acts described above, the Defendants individually by and through their own acts, or through the acts of their agents, servants, officers, and employees, knowingly made, used, and/or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by Medicare, Medicaid, and TRICARE, in violation of 31 U.S.C. §3729(a)(1)(B).

95. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

96. Additionally, the United States is entitled to penalties of up to $11,000 for each and every violation of 31 U.S.C. §3729(a)(1)(B)) by the Defendants.

THIRD CLAIM FOR RELIEF
(CIVIL CONSPIRACY TO COMMIT VIOLATIONS
OF THE FALSE CLAIMS ACT – 31 U.S.C. §3729(a)(1)(C))

97. The allegations of all paragraphs in this Complaint are incorporated by reference.

98. The Defendants conspired and confederated to commit violations of the False Claims Act, 31 U.S.C. §3729, including having conspired and confederated to have knowingly presented false or fraudulent claims for payment or approval; having knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims; and having knowingly made, used, or caused to be made or used, false

records or statements material to an obligation to pay or transmit money or property to the Government, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

99. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

100. Additionally, the United States is entitled to penalties of up to $11,000 for each and every violation of 31 U.S.C. §3729(a)(1)(B)) by the Defendants.

FOURTH CLAIM FOR RELIEF
(VIOLATION OF THE ANTI-KICKBACK ACT, 41 U.S.C. §53)

101. The allegations of all paragraphs in this Complaint are incorporated by reference.

102. The Defendant CMHA, in providing services to the United States Government, illegally and unlawfully offered and then provided kickbacks to Defendant MNA in exchange for referral of additional patients and services which were ultimately billed to and paid for by the United States Government.

103. The Defendant MNA illegally and unlawfully accepted kickbacks offered and paid to them by Defendant CMHA in providing services to the United States Government.

104. As a result of the Defendants' fraudulent conduct, the United States government has been damaged in amounts to be determined at trial.

105. Additionally, the United States is entitled to penalties of up to $11,000 for each and every violation of 31 U.S.C. §3729(a)(1)(B)) by the Defendants.

FIFTH CLAIM FOR RELIEF
(RETALIATION – 31 U.S.C. §3730(h))

106. The allegations of all paragraphs in this Complaint are incorporated by reference.

107. In performing the acts described above, the Defendant CMHA by and through its own acts, or through the acts of its agents, servants, officers, and employees, unlawfully retaliated against Relator in violation of 31 U.S.C. §3730(h).

108. Specifically, the Defendant CMHA terminated Relator for engaging in protected activity pursuant to 31 U.S.C. §3730(h). As a result of the Defendant CMHAs' unlawful retaliation, Relator has suffered damages in amounts to be determined at trial.

SIXTH CLAIM FOR RELIEF
(BREACH OF CONTRACT)

109. The allegations of all paragraphs in this Complaint are incorporated by reference.

110. This Court has supplemental jurisdiction over this claim under 28 U.S.C. §1367, because this claim is so related to claims in the action within the Court's original jurisdiction that it forms part of the same case or controversy under Article III of the United States Constitution.

111. At the time of his termination, Relator had a valid contract of employment with Defendant CMHA (the "Employment Contract").

112. Defendant CMHA breached the Employment Contract.

113. Relator has been damaged by Defendant CMHA's breach, and is entitled to recover monetary damages according to his proofs.

PRAYER FOR RELIEF

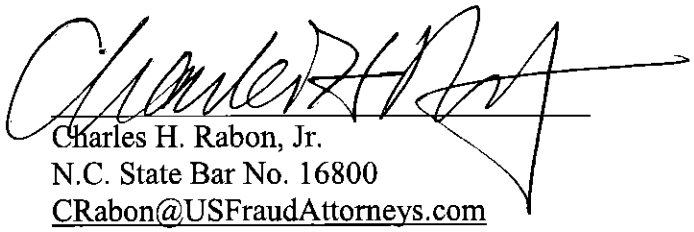
Relator, on behalf of himself and the United States Government, prays as follows:

1. That for violations of the Federal False Claims Act, 31 U.S.C. §3729, *et seq.*, this Court enter Judgment against the Defendants, jointly and severally, in an amount equal to three times the amount of damages the United States Government has sustained because of

Defendants' actions, plus a civil penalty of $11,000 for each action in violation of 31 U.S.C. §3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

2. That the Relator be awarded all costs incurred, including reasonable attorneys' fees;
3. That, in the event the United States Government, continues to proceed with this action, the Relator be awarded an amount for bringing this action of 25% of the proceeds of the action or settlement of the claim, or the maximum allowed under applicable law;
4. That, in the event that the United States, does not proceed with this action, the Relator be awarded an amount that the Court decides is reasonable for collecting the civil penalty and damages in the amount of 30% of the proceeds of the action or the settlement, or the maximum allowed under applicable law;
5. That Defendants be found to have violated and be enjoined from future violations of 31 U.S.C. § 3730(h);
6. That Relator be awarded all relief to which he is entitled pursuant to §3730(h) of the False Claims Act;
7. That Relator have and recover all damages for Defendant CMHA's breach of Relator's employment contract, according to proof;
8. That Relator be awarded all costs of this action, together with all expert witness fees, attorneys' fees, and court costs, as fully as is allowed by law;
9. That the Relator be awarded prejudgment interest;
10. That a trial by jury be held on all issues; and

11. That the United States Government, and the Relator, receive all relief, both in law and in equity, to which they may reasonably appear entitled.



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